ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

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President & CEO

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October 9, 2000

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

VIA FACSIMILE – 202-690-7203

Dear Madam Secretary:

Since unveiling its "Framework" document almost three years ago, the Food and Drug Administration's Center for Veterinary Medicine has been conducting a review of the approval protocol for antibiotics used to treat disease in food animals. The Animal Health Institute has participated in every activity sponsored by the agency that offered the opportunity for public comment on aspects of the "Framework", including the development of a comprehensive and flexible risk assessment model. In order to provide additional information on the risk assessment model being developed by CVM, AHI supported the activities of Dr. Tony Cox, a distinguished and highly regarded risk assessor previously retained by the CVM to evaluate CVM's Risk Assessment model's ability to estimate and manage the risk associated with the use of fluoroquinolones in poultry.

AHI offered to collaborate with CVM through direct interaction of the risk assessor AHI retained, and the risk assessor who worked for CVM on its risk assessment. AHI believes that these offers – set forth in letters to FDA – are very much in the spirit of FDA's desire to leverage its resources through partnerships. Furthermore, our efforts appear to be consistent with statements made by CVM's Director and Associate Director for Veterinary, Medical and International Affairs. Indeed, CVM acknowledged the value of Dr. Cox's modifications to the model during a recent risk assessment symposium at Harvard University. Notwithstanding those comments, significant exchange of information between Dr. Cox and CVM's risk modeler has yet to take place.

We believe that Dr. Cox has clearly demonstrated that there are profound weaknesses in the model that CVM has embraced. These weaknesses translate into severe shortcomings and make the framework questionable as a public policy tool. The risk assessment model developed by CVM is not capable of analyzing the health impacts of public policy that could result from the actions of either FDA or other agencies charged with safeguarding the public health. In fact, the CVM model, as currently designed, is merely a review of historical data and does not allow any modification of the variables traditionally utilized by the agency to protect human health and ensure efficacy. The risk assessment contemplates only the single action of product removal and provides no opportunity to predict or measure the success of that action in safeguarding human health.

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The design of the risk assessment model is critical both in terms of its immediate impact on the use of fluoroquinolones to treat disease in food animals and the use of the model as a template for future risk assessment activities. We are troubled by the recent statements from CVM that the risk assessment on fluoroquinolone use in poultry is likely to be finalized in the coming weeks without modifications which we know – based on expert analysis – to be essential.

Our concern is heightened by the probability that the agency will initiate a significant action against an approved product based primarily on a risk assessment that is clearly flawed, incomplete and subject to criticism from experts. Given the possibility that FDA may take action soon, your urgent attention to this matter is needed.

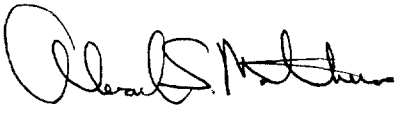
It is important to remember that the particular fluoroquinolone subject to review was approved for use in poultry after exhaustive testing by the agency. Furthermore, use of the product is allowed only under veterinary prescription with restrictions against extra-label use. In the five years since the approval of the first fluoroquinolone for use in food animals, the National Antimicrobial Monitoring Program has revealed no significant increase in the development of salmonella or campylobacter resistance. In fact, the 1999 NARMS data for animal isolates indicates a declining incidence of fluoroquinolone resistant campylobacter.

We believe that it is imperative that CVM complete its risk assessment on the use of fluoroquinolones in poultry only after the current modeling effort is reviewed by additional risk assessment experts. An outside review by risk assessment experts or by the GAO will reveal whether the CVM model can provide an analysis of public policy alternatives, including suspension of the use of an approved product.

We are very concerned that the failure of CVM to directly address questions surrounding its risk assessment model is likely to have significant consequences for the continued availability of antibiotics to treat animals with no measurable connection to improvements in public health.

It is our goal to continue to address the need for antibiotics to protect animal health without compromising human health and we look forward to working with CVM in that spirit of concern and cooperation.

Sincerely,



Alexander S. Mathews

CC: The Honorable Jane E. Henney, M.D.
Dr. Stephen Sundlof, CVM Director